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Tom Jacob
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Austin, TX 78745

Re: Byrd Stroke Case, Supplemental Report

Dear Mr. Jacob:

I am writing a supplemental report. I have reviewed my previous report (dated June 19, 2019). My opinions on the medical records remain the same.

Since my previous report, I have reviewed:

- The depositions of Drs. Goracy, Jabaley, and Yepes. Please note, since these depositions occurred recently and I understand we have a deadline to disclose my opinions, I have received preliminary transcripts. I reserve the right to further supplement my opinions after receiving final transcripts.
- Delirium Protocol (2015) (USAO_BYRD_11236-42)
- Management & Treatment of Acute Ischemic Stroke (Sept 14, 2016) (USAO_BYRD_11257-273)
- Protocol for the Care of the Post-Surgical Patient (USAO_BYRD_11274-280)
- t-PA for suspected Ischemic Stroke (2014) (USAO_BYRD_11281-291)
- Management & Treatment of Acute Ischemic Stroke (2019) (USAO_BYRD_11243-256)
- VA Stroke Posters (USAO_BYRD_14308-309)

I have received additional medical records and imaging from the United States through discovery, though there seems to be much overlap between the records from the United States and the records Mr. Byrd originally provided me. I reserve

the right to use these records and images to demonstrate the opinions I have outlined in my previous report as well as this report. Like the previous report, all of the opinions that I have reached in this report are to a reasonable degree of medical certainty. Should I be given additional documents or asked other questions, I reserve the right to further supplement my opinions.

Ruling Out Stroke

Multiple providers agreed that the standard of care required ruling out life threatening causes of a patient's presentation. (GORACY pg. 44, YEPES pg. 31-32, JABALEY, pg. 35). The Delirium Protocol and the providers agree identifying the cause of delirium is the first step in delirium management. (GORACY pg. 47, YEPES pg. 28, JABALEY, pg. 35, USAO_BYRD_11237). And if providers suspect stroke, they must rule out stroke. (GORACY pg. 122, JABALEY, pg. 34) Patients with signs or symptoms consistent with acute ischemic stroke must be evaluated emergently. (GORACY pg. 48, JABALEY, pg. 34) That's because stroke is a life threatening condition and every minute matters to a stroke patient. (GORACY pg. 44, USAO_BYRD_14309). As I understand it, the VA had a stroke team that should be called for suspected strokes. (GORACY pg. 47-48, JABALEY, pg. 33-34, YEPES pg. 36).

Moreover, at least as of Nov. 22, stroke was on the provider's differential as the cause of Mr. Byrd's acute change in mental status. (GORACY pg. 111). However, even though Mr. Byrd began presenting with delirium between Nov. 15 and 16th, the providers testified that as of Nov. 23rd, they did not know the cause of Mr. Byrd's presentation. (GORACY pg. 107-108).

The providers testified that Mr. Byrd's presentation was multifactorial. For example, that he had symptoms that could be attributable to both medications and stroke. However, as the treating doctors admit, when two things present similar, providers should still rule out life threatening conditions. (GORACY pg. 54-57, 122, YEPES pg. 46-47).

Delirium & Stroke

In the depositions, the treating providers do not seem to believe stroke can cause delirium, which is contrary to available literature. They do, however agree that sudden confusion can be a sign of stroke. (YEPES pg. 46, GORACY pg. 52, JABALEY, pg. 39).

Further, neither Dr. Goracy nor Dr. Yepes seemed to recognize that the patient was aphasic on Nov. 22nd, 2016. On this date, it is likely that Mr. Byrd was agitated because he could not communicate as sometimes may happen in aphasic patients.

While Dr. Goracy doesn't believe that Mr. Byrd is substituting words, she testified that Mr. Byrd is speaking in sentences that do not make sense and he's not able to understand other people's conversation. (GORACY pg. 91). And she admits in deposition that aphasia presents exactly like this. (GORACY pg. 51-52).

Finally, because no adequate examination was performed, we are unable to tell what other symptoms of stroke that Mr. Byrd had. For example, even though the VA's policies require an NIH Stroke Scale to be performed, I could not find any such examination done. The VA Policies require an NIH Stroke scale performed on all suspected strokes. (USAO_BYRD_11243, USAO_BYRD_11268 — within 45 minutes for tPA patients and 24 hours for those falling outside the tPA window.) An example NIH Stroke Scale can be found in the VA policies on stroke between USAO_BYRD_11249-250 (pgs. 7-8 of the stroke policy).

Dr. Goracy was unaware of any NIH Stroke Scale being performed on Mr. Byrd. (GORACY pg. 113). Dr. Yepes testified he did not see one in the chart. (YEPES pg. 91).

If we look at the records on Nov. 22, however, Mr. Byrd would have scored a minimum of 6 on the NIH Stroke Scale.

- Mr. Byrd had a sudden, acute change in mental status. (GORACY pg. 93-94).
- Mr. Byrd was also slurring his words, as reported in the medical record. Both Dr. Boyer and Dr. Goracy observed Mr. Byrd slurring his words. (GORACY pg. 87). This adds **1 point** to his Stroke Scale.
- The records also document aphasia. For example, in response to asking him his name and age, he replies, "Pool dog train is bag going to." (GORACY pg. 89). In response to the question "Where are we right now?", Mr. Byrd replies "I'm people ton." (GORACY pg. 89-90). In response to "Where are we now?" Mr. Byrd replies "know the human." (GORACY pg. 90). This adds **1 points** to his stroke scale.
- On this date, we know that Mr. Byrd was not oriented to person, place, or time. (GORACY pg. 82-83, GORACY pg. 89-90, asking about date). This lack of orientation could give Mr. Byrd an additional **2 points**. The stroke scale asks the patient the month and their age. If they answer only one incorrectly, they are given one point. If they answer neither incorrectly, they are given two points. Mr. Byrd was asked the month and date, to which he responded "human." (GORACY pg. 90). He was also not oriented to the person. (GORACY pg. 82).

- In addition, he was following commands “intermittently”, although likely mimicking, suggesting severe aphasia (Schultz/Yepes, pg. 903, Atlanta VA 1 file). This will add **2 points** to his stroke scale.

So, based on this review of the record, Mr. Byrd had a NIH stroke scale of 6 on Nov. 22, 2016. Because a focused exam relating to possible stroke was not performed, we cannot be sure what other deficits that Mr. Byrd had at the time. NIH Stroke scale of 6 is usually suggestive of a large vessel abnormality unless ruled out otherwise. The NIH Stroke scale can be administered in less than 10 minutes in skilled hands. It provides an excellent baseline for stroke treatment assessment and can be used for prognosis.” (USAO_BYRD_11250).

Waxing & Waning Presentation

Dr. Yepes testified that because Mr. Byrd’s delirium waxed & waned, that Mr. Byrd was not having a stroke. First, we know this not to be the case because the MRI/MRA taken on Nov. 25, 2016 definitely proves that Mr. Byrd had a stroke. (NTL1103-1102). Moreover, Dr. Yepes testified that based on his review of the images, that this stroke was anywhere from 5-10 days old. (YEPES pg. 70-71). So, since the MRI was taken on Nov. 25, the earliest this stroke could have occurred, in Dr. Yepes view, is Nov. 15, the day of Mr. Byrd’s operation. According to Dr. Yepes, the latest the stroke could have happened is Nov. 18th, 2018.

However, Dr. Yepes timing of the stroke does not fit the presentation. For example, following the surgery on Nov. 15, 2016, Mr. Byrd exhibited signs of delirium as discussed previously. Over the course of the next 7 days, however, Mr. Byrd’s delirium does diminish over time. At 08:00 on Nov. 22, 2016, Mr. Byrd wakes up alert and oriented to his surroundings. He tells the nurse, “I want to go home, I’m tired of being here.” (NTL1324). At 10:40 am, he’s able to demonstrate independent mobility, balance, and he seems to follow instructions with his physical therapist. (NTL1324). At 10:47 am, he’s able to follow the instructions of his occupational therapist, including ambulating, transferring to and from bed, and performing grooming activity (brushing his teeth) with supervision. (NTL1322). Then, at some time after 11 am, a code 44 is called for sudden confusion and extreme agitation. (NTL1322–20). Psychiatry was called and noted that the patient was “A&Ox3 and was being considered for discharge” until this sudden shift change in behavior to A&Ox0. (NTL1322-23). Given Dr. Yepes the benefit of the doubt, if there was a major stroke event as late as Nov. 18, why did it take until Nov. 22nd to manifest?

Instead, more likely than not, Mr. Byrd suffered an initial self-limited stroke on Nov. 15, 2016, injuries being limited due to the clot having dissolved rapidly. Mr.

Byrd appears to have return to closer to his baseline afterwards. Mr. Byrd likely suffered from another event on Nov. 22, 2016, which resulted in his aphasia due to clot that remained lodged in the M2 division of the MCA, as noted on the MRI/MRA. (NTL1103-04). This is “large vessel stroke,” in the left posterior MCA with proximal M2 cutoff. (NTL1243-44). The etiology of both the events was likely cardioembolic.

These types of strokes can be caused by intermittent atrial fibrillation. Dr. Yepes testified that the combination of medications that Mr. Byrd was can cause transient atrial fibrillation. (YEPES pg. 115.) After providers diagnosed Mr. Byrd’s stroke, they ran carotid Doppler to rule out stenosis. (YEPES pg. 107-108). They also ran a TTE to identify structural defects of the heart. (YEPES pg. 109). After looking at the doppler, the TTE, and the telemetry, providers top suspicion was cardioembolic stroke. (NTL866) While no a-fib was found on telemetry, Dr. Yepes testified that telemetry cannot rule out paroxysmal atrial fibrillation. (YEPES pg. 115). He testified that to rule out transient atrial fibrillation, you need at least 30 days of continuous heart monitoring within 6 months of their discharge. (YEPES pg. 115).

Transient atrial fibrillation is consistent with the fact that Mr. Byrd later suffered from syncope episodes.¹ (USAO_BYRD_3293, cardiology consult for Syncope) This record notes that “Patient has had multiple episodes of syncope. 8 per patient, although documentation state[s] less. Regardless, patient has had recurrent issues. This started after he had back surgery in November of 2016. He suffered a L MCA CVA with residual deficits.” In response, providers gave him Holter monitoring. Even though Dr. Yepes testified that he recommended outpatient Holter monitoring, the only Holter monitoring I could find in the record was in May of 2017, following Mr. Byrd’s syncope episode. (USAO_BYRD_3293). There, the Holter monitoring was provided for only 6 days, instead of the 30 day that Dr. Yepes recommends.

Thrombectomy

Dr. Yepes incorrectly testified that there were no studies supporting the effectiveness of thrombectomy in 2016 as guidelines published by American Stroke Association in June, 2015 clearly specified the role of intraarterial thrombectomy in eligible patients on the basis of multiple studies (<https://www.ahajournals.org/doi/10.1161/str.0000000000000074>). Thrombectomy for the treatment of strokes had become a standard of care in eligible patients

¹ Brignole, Michele, et al. “Role of autonomic reflexes in syncope associated with paroxysmal atrial fibrillation.” *Journal of the American College of Cardiology* 22.4 (1993): 1123-1129.

Malik, Varun, et al. “Atrial fibrillation is associated with syncope and falls in older adults: a systematic review and meta-analysis.” *Mayo Clinic Proceedings*. Vol. 95. No. 4. Elsevier, 2020.

across the United States in 2016. For this to occur, patients routinely underwent CT angiography that would be followed by consideration of thrombectomy in eligible patients. I would expect a reasonable provider treating Mr. Byrd in 2016 to expedite vascular studies with corresponding thrombectomy to preserve brain function following his stroke. It is to be noted that tPA would have been a relative contraindication given his recent surgery, however, thrombectomy would have been indicated given his vascular imaging findings.

Dr. Yepes' CV cites two studies from 2010. First, Dr. Yepes contributed to an article that supported my previous report's discussion that had the VA intervened, they could have preserved brain function in Mr. Byrd. Shi, Zhong-Song, et al. "Clinical outcomes in middle cerebral artery trunk occlusions versus secondary division occlusions after mechanical thrombectomy: pooled analysis of the Mechanical Embolus Removal in Cerebral Ischemia (MERCI) and Multi MERCI trials." *Stroke* 41.5 (2010): 953-960. This article was citation #43 in Dr. Yepes' CV. (USAO_BYRD_011312)

The results of this study conclude "that patients presenting with MCA M1 occlusions or isolated M2 occlusions can achieve high revascularization rates and favorable clinical outcomes after mechanical thrombectomy with the Merci devices. Patients with isolated M2 occlusions achieved a higher revascularization rate and were associated with a trend of a shorter median procedure time." Mr. Byrd suffered from an isolated M2 occlusion and the study found an "82% revascularization rate" in those cases, which was "significantly higher than other sites of occlusions."

Second, Dr. Yepes contributed to another study (citation 42 on his CV) that found revascularization rates did not differ even for patients who had previously been provided tPA. (USAO_BYRD_011312) Shi, Zhong-Song, et al. "Endovascular thrombectomy for acute ischemic stroke in failed intravenous tissue plasminogen activator versus non-intravenous tissue plasminogen activator patients: revascularization and outcomes stratified by the site of arterial occlusions." *Stroke* 41.6 (2010): 1185-1192.

The authors conclude, "We found no difference in good outcomes and mortality between patients undergoing mechanical thrombectomy after failing or being ineligible for IV tPA." This article also cites multiple other articles, noting, "Previous endovascular studies have shown a strong association between successful revascularization and favorable clinical outcomes [citing 5 other studies and our analysis supports this assertion. In the non-IV tPA group, revascularized patients had a higher proportion of good outcomes and a lower rate of mortality. In

addition, patients with revascularized MCA or basilar occlusions had better outcomes and less mortality than the nonrevascularized patients in both groups.”

These two studies which Dr Yepes contributed to were important in suggesting the role of thrombectomy.

Studies since 2016 only re-affirm what was known then. A very recent study examining treatment in stroke patients with M2 segment occlusion of the MCA presenting with mild neurological deficits found “no difference in favorable outcome” in patients given mechanical thrombectomy only compared to intravenous thrombolysis.² A patient in Mr Byrd’s case who may be tPA ineligible due to his recent surgery would have benefitted from a consideration of thrombectomy if his aphasia were promptly diagnosed and investigations done as such.

It is my belief that at the very minimum, Mr. Byrd and his family should have been given the opportunity to decide to undergo this intervention to preserve brain function. And had Mr. Byrd underwent a thrombectomy, more likely than not, his current deficits would have been avoided based on my experience and qualifications, the medical records, and my survey of the literature. Additionally, by failing to diagnose the initial transient ischemic attack between Nov. 15-22, the VA providers failed to activate secondary stroke prevention, which would have avoided the much larger MCA M2 stroke on Nov. 22 altogether. Dr. Yepes testified that secondary prevention means were not given to Mr. Byrd until Feb. 25. (YEPES pg. 104).

Should you have any questions about this matter, please do not hesitate to reach out to me.

Sincerely,

A handwritten signature in black ink, appearing to read 'Abhay Kumar'.

Abhay Kumar, M.D.

² <https://www.ahajournals.org/doi/10.1161/STROKEAHA.120.031672>